

TSU-004

advancing a septal defect occluder having proximal and distal ends with a shape memory frame and a biodegradable/biocompatible member through the catheter;

allowing the distal end of the occluder to form a preset shape in the left side of the heart;

withdrawing the catheter and the occluder slowly until the distal end contacts the heart tissue around the opening of the defect;

withdrawing the catheter until the occluder is fully deployed in the heart and the proximal end has formed its preset shape;

removing the catheter from the patient;

allowing the body to degrade the biodegradable member and cover the frame with native tissue.

**REMARKS IN REGARD TO 35 USC §112, SECOND PARAGRAPH**

Claims 1-2, 5, 7, 10-12, 15, 17, 20, and 23 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1, 7, 10-12, 17, 20, and 23 have been amended to reflect the examiner's suggestion to use the term "biodegradable and/or biocompatible."

In Claims 5 and 15 the term "Nitinol" has been changed to read "a Nickel Titanium Alloy material."

**REMARKS IN REGARD TO 35 USC §102(b)**

Claims 1-2, 5, 7, 11, 12, 15, 17, 20, and 23 stand rejected under 35 USC §102(b) as being unpatentable over U.S. Patent Number 5,853,422. (Huebsch et al.) Claim 1 has

TSU-004

been amended to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The amendment to the claim finds support in the claim language. The Applicant reminds the Examiner that MPEP 213.06 states, "information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." (Emphasis Added.)

The amended claim deletes reference to discs and more particularly points out that the ribs of the umbrella "bending toward said midpoint" allowing the ribs to stabilize the device with respect to the tissue. In contrast, Huebsch simply places the device flush against the surface of the tissue.

The Applicant has amended claim 1 to overcome the 35 USC § 102 rejection. Huebsch does not disclose, teach, or otherwise suggest a ribs which bend toward the midpoint of the device. Therefore, since Huebsch does not disclose ribs bending toward a midpoint, claims 1-2, 5, 7, 11, 12, 15, 17, 20, and 23 are now in a condition for allowance.

#### **REMARKS IN REGARD TO 35 USC §103(a)**

Claims 10 and 20 stand rejected under 35 USC §103(a) as being unpatentable over U.S. Patent Number 5,853,422 (Huebsch et al.) and U.S. Patent Number 6,143,037 (Goldstein et al.) Since, claims 10 and 20 both depend from allowable claims as above, claims 10 and 20 are now in a condition for allowance.

#### **CONCLUSION**

TSU-004

An additional fee for a three month extension is being submitted with the present response.

On the basis of the above remarks, early consideration of this application and early allowance are respectfully requested.

Respectfully,

By: 

Edward M. Bushard  
Agent for Applicant  
Reg. No. 48,974

Date: June 14, 2004

Edward M. Bushard  
3221 19<sup>th</sup> St.  
Sacramento, California 95818

Telephone: (916) 402-4900  
Facsimile: (916) 444-1717